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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/604,114 | 06/26/2000 | David J. Farrar | | 3775 |

7590 01/14/2003

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|---------------|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/604,114 | | FARRAR, DAVID J. | |
| | Examiner | | Art Unit | |
| | | Julian W. Woo | 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41-57 is/are allowed.
- 6) ☒ Claim(s) 1-5, 12, 13, 15, 16, 18, 19, 21, 22, 24, 25, 27-31 and 38-40 is/are rejected.
- 7) ☒ Claim(s) 6-11, 14, 17, 20, 23, 26 and 32-37 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 05 November 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 2, 12, 13, 15, 16, 18, 19, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg et al. (3,318,511). With respect to claims 1, 2, 18, 19, 21, and 22, Goldberg et al., in figures 1 and 3, disclose a monolithic graft with a tubular portion (2) and a flared portion (1) with an elongated, circumferential skirt (3), where the central axes of each of the portions are parallel and the flared end of the flared portion has an internal diameter greater than an internal diameter of the tubular portion. With respect to claims

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12, 13, 15, 16, figure 4 and col. 6, lines 9-14 disclose a flared end with a central axis that is oblique to the central axis of the tubular portion, so that the skirt would be oriented for attachment at an acute angle to a blood vessel.

3. Claims 1-5, 24, 25, 27-31, 38, 39, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Yang et al. (5,989,287). With respect to claims 1-6, 25, 27-31, 39, and 40, Yang et al.; in figures 1B-2B, in col. 5, line 64 to col. 6, line 18, and in col. 6, line 51 to col. 7, line 30, disclose a monolithic, polyurethane graft with a tubular portion (at 30) and a flared portion (26) with an elliptically-shaped, circumferential skirt (28) or an asymmetrically flared end, where the flared end is oblique to the central axis of the tubular portion, where the flared end has an internal diameter greater than an internal diameter of the tubular portion, and the skirt is attached at an acute angle to a blood vessel. With respect to claim 24, col. 5, line 66 to col. 6, line 4 disclose a fabric mesh as a reinforcing member.

Response to Amendment

4. With respect to the arguments regarding the "informalities and indefiniteness rejections": The objections and rejections are hereby withdrawn.

With respect to the arguments regarding the "enablement rejection": The rejection is hereby withdrawn.

With respect to the arguments regarding the "anticipation rejections" based on references, "Goldberg" and "Yang": The adjoining end of the flared portion of each of these prior art devices is indeed, as stated in the claim, "integrally formed on... said second end of said tubular portion." That is, the

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flared portion and the tubular portion are joined or integrated to form a unitary graft.

With respect to the arguments regarding the "obviousness rejections":

The rejections are hereby withdrawn.

Allowable Subject Matter

5. Claims 41-57 are allowed.

6. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a method of manufacturing a bypass graft, where at least one layer of polyurethane is formed over a mandrel having a tubular portion and a flared end bulb with a flared end central axis.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Claims 6-11, 14, 17, 20, 23, 26, and 32-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a graft formed with at least a layer of polyether urethane-urea with an additive

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having, in a weight range of 1% to 5%, a combination of MDI, polydimethylsiloxane, and 1,4-butanediol; and where the polyether urethane-urea is end-capped with dibutylamine.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

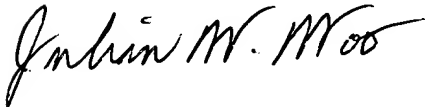
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9302.

A handwritten signature in black ink that reads "Julian W. Woo". The signature is written in a cursive, flowing style.

Julian W. Woo
Patent Examiner

January 10, 2003